Complete Summary

GUIDELINE TITLE

Cervical incompetence.

BIBLIOGRAPHIC SOURCE(S)

Cervical incompetence. Philadelphia (PA): Intracorp; 2005. Various p. [13 references]

GUIDELINE STATUS

This is the current release of the guideline.

All Intracorp guidelines are reviewed annually and updated as necessary, but no less frequently than every 2 years. This guideline is effective from July 1, 2005 to July 1, 2007.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Cervical incompetence

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention
Treatment

CLINICAL SPECIALTY

Obstetrics and Gynecology

INTENDED USERS

Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Utilization Management

GUIDELINE OBJECTIVE(S)

To present recommendations for the diagnosis and management of cervical incompetence that will assist medical management leaders to make appropriate benefit coverage determinations

TARGET POPULATION

Pregnant women with cervical incompetence

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Physical examination, medical history, and assessment of signs and symptoms
2. Diagnostic tests:
    - Ultrasound (US)
    - Hysterosalpingogram and examination of the cervix with dilators (not to be employed during pregnancy)
    - Presence of fibronectin in vaginal secretions

Note: The following measures are not recommended because of lack of data or lack of efficacy:

- Salivary estriol, home uterine activity monitoring (HUAM), or bacterial vaginosis screening as strategies to identify or prevent preterm birth
- Screening for risk of preterm labor in the general population by means other than historic risk factors

Management/Treatment/Prevention

1. Cervical cerclage
2. Prolonged hospitalization with cervical cerclage, perioperative antibiotics, Trendelenburg position
3. Transabdominal cerclage with subsequent decreased activity and extended bed rest
4. Cerclage removal

MAJOR OUTCOMES CONSIDERED

- Utility of diagnostic tests
- Risk of pre-term delivery
- Morbidity and mortality associated with pre-term birth
- Effectiveness of surgical and non-surgical modalities used to treat cervical insufficiency and prevent pre-term birth
- Complications of surgical treatment of cervical insufficiency

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches were performed of the following resources: reviews by independent medical technology assessment vendors (such as the Cochrane Library, HAYES); PubMed; MD Consult; the Centers for Disease Control and Prevention (CDC); the U.S. Food and Drug Administration (FDA); professional society position statements and recommended guidelines; peer reviewed medical and technology publications and journals; medical journals by specialty; National Library of Medicine; Agency for Healthcare Research and Quality; Centers for Medicare and Medicaid Services; and Federal and State Jurisdictional mandates.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A draft Clinical Resource Tool (CRT or guideline) is prepared by a primary researcher and presented to the Medical Technology Assessment Committee or the Intracorp Guideline Quality Committee, dependent upon guideline product type.

The Medical Technology Assessment Committee is the governing body for the assessment of emerging and evolving technology. This Committee is comprised of a Medical Technology Assessment Medical Director, the Benefit and Coverage Medical Director, CIGNA Pharmacy, physicians from across the enterprise, the Clinical Resource Unit staff, Legal Department, Operations, and Quality. The Intracorp Guideline Quality Committee is similarly staffed by Senior and Associate Disability Medical Directors.

Revisions are suggested and considered. A vote is taken for acceptance or denial of the CRT.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

<u>Diagnostic Confirmation</u>

Subjective Findings

- Symptoms of a spontaneous abortion which include the following:
  - Uterine cramping
  - Vaginal bleeding

    - Passage of the products of conception
- History of prior cervical trauma

Objective Findings

- History of prior pregnancy with incompetent cervix
- Cervical shortening after the application of transfundal pressure
- History of prior spontaneous mid-semester abortion
- Painless dilatation of the cervix found on physical examination

Indications

Summary of American College of Obstetricians and Gynecologists (ACOG) Recommendations on Assessment of Risk Factors for Preterm Birth

The following recommendation from the ACOG committee is based on good and consistent scientific evidence (Level A):

- There are no current data to support using salivary estriol, home uterine activity monitoring (HUAM), or bacterial vaginosis screening as strategies to identify or prevent preterm birth.

The following ACOG recommendations are based on limited or inconsistent scientific evidence (Level B):

- Screening for risk of preterm labor by means other than historic risk factors is not beneficial in the general obstetric population.
- Ultrasonography to determine cervical length, fetal fibronectin testing (FT), or a combination of both may be useful in identifying women at high risk for preterm labor. However, their clinical usefulness may rest primarily with their negative predictive value, given the lack of proven treatment options to prevent preterm birth.
- FT may be useful in women with symptoms of preterm labor to identify those with negative values and a reduced risk of preterm birth, thereby avoiding unnecessary intervention.

Diagnostic Tests

- Ultrasound (US):
    - Ultrasound is very useful in evaluating cervical changes in pregnancy; ultrasonographic findings of cervical insufficiency include a cervical length of less than 20 mm and funneling of the internal os. For the majority of women who present with a complication (e.g., membrane rupture, or with an uncertain history) ultrasound can be an important diagnostic tool used to confirm a difficult diagnosis.
    - Frequent transvaginal ultrasounds can be used to monitor for cervical shortening or funneling in women with an uncertain diagnosis in their first or second trimester.
- Hysterosalpingogram (radiologic study involving the visualization of the uterus and oviducts after the injection of a radio-opaque material) and examination of the cervix with dilators may help confirm the diagnosis, but is

not used as a sole diagnostic test. (NOTE: NOT to be employed during pregnancy)
- Presence of fibronectin in vaginal secretions (a high level may suggest eminent preterm labor)

Differential Diagnosis

- Chorioamnionitis
- Fetal malformations
- Placental malformations
- Abruptio placentae
- Placenta previa
- Uterine anomalies
- Fetal death
- Retained intrauterine device
- Systemic maternal illness
- Multiple gestation

Treatment

Treatment Options

- The primary treatment option is cervical cerclage, a surgical procedure to strengthen the cervix.
    - The most common type of cerclage is the McDonald cerclage, in which a purse string suture is inserted at the cervicovaginal junction.
- For women with the diagnosis of cervical insufficiency, a prophylactic cerclage is indicated in the first trimester; ACOG has published guidelines for prophylactic cerclage - these include:
    - Prior pregnancy with incompetent cervix
    - Pre-pregnancy physical findings suggesting possible cervical incompetence in a patient with a history of prior spontaneous midtrimester abortion
- Following prophylactic cerclage, the following are contraindicated:
    - Sexual intercourse
    - Heavy exertion
    - Prolonged standing
- For women who present unexpectedly with cervical insufficiency in the second trimester, hospitalization is necessary and the intervention depends on the degree of dilatation. If sufficient cervical length remains, a cerclage can be placed and the patient monitored for only 2 to 4 days in the hospital. If membranes are visible, prolonged hospitalization with cerclage, perioperative antibiotics, and even Trendelenburg positioning may be necessary.
- For women who fail a prophylactic vaginal cerclage, abdominal cerclage may be necessary, also known as a transabdominal cerclage. Following abdominal cerclage, substantially decreased activity and extended periods of bed rest are indicated.
- Cerclages are rarely indicated following 26 weeks of gestation as delivery may be delayed with other conservative measures such as bed rest and tocolytics, which do not carry the same risk of inducing preterm labor or membrane rupture.

- All cerclages should be removed at 37 weeks gestation if successfully reached.

Duration of Medical Treatment

- Medical
    - Women with cervical insufficiency require treatment until delivery. The extent of the intervention depends on the degree of insufficiency and the gestational age.

Additional information regarding referral options and specialty care is provided in the original guideline document.

The original guideline document also provides a list of red flags that may affect disability duration, and return to work goals, including

- After prophylactic cervical cerclage
- After hospitalization for cervical insufficiency during second trimester
- After hospitalization for cervical insufficiency during third trimester
- After vaginal delivery

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis and management of cervical incompetence that assist medical management leaders to make appropriate benefit coverage determinations

POTENTIAL HARMS

Transabdominal cerclage can be complicated by rupture of membranes and chorioamnionitis. It carries the added risk of intraoperative hemorrhage from the uterine veins when the cerclage band is tunneled between the bifurcation of the uterine artery, as well as the known risks associated with laparotomy. Life-threatening complications of uterine rupture and maternal septicemia are extremely rare but have been reported with all types of cerclage.

CONTRAINDICATIONS

CONTRAINDICATIONS

Therapeutic cerclage beyond 34 weeks' gestation is not recommended, because of fetal viability concerns and potentially causing a preterm delivery while placing the cerclage.

Following prophylactic cerclage, the following are contraindicated:

- Sexual intercourse
- Heavy exertion
- Prolonged standing

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Cervical incompetence. Philadelphia (PA): Intracorp; 2005. Various p. [13 references]

ADAPTATION

The guideline recommendations are partially adapted from:

- American College of Obstetricians and Gynecologists (ACOG). Assessment of risk factors for preterm birth. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2001 Oct. 8 p. (ACOG practice bulletin; no. 31). [80 references]

DATE RELEASED

2005

GUIDELINE DEVELOPER(S)

Intracorp - Public For Profit Organization

SOURCE(S) OF FUNDING

Intracorp

GUIDELINE COMMITTEE

CIGNA Clinical Resources Unit (CRU)
Intracorp Disability Clinical Advisory Team (DCAT)
Medical Technology Assessment Committee (MTAC)
Intracorp Guideline Quality Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Intracorp guidelines are available for a licensing fee via a password protected, secure Web site at www.intracorp.com.

Reprints of complete guideline content may be purchased for $35.00 per title (plus tax in TX at 8.25% and CT at 1.0%). Please send e-mail request to lbowman@mail.intracorp.com.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Policies and procedures. Medical Technology Assessment Committee Review Process. Philadelphia (PA): Intracorp; 2004. 4 p.

- Online guideline user trial. Register for Claims Toolbox access at www.intracorp.com.

Licensing information and pricing: Available from Intracorp, 1601 Chestnut Street, TL-09C, Philadelphia, PA 19192; e-mail: lbowman@mail.intracorp.com.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on August 9, 2005. The information was verified by the guideline developer on August 31, 2005.

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DISCLAIMER

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